IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MERCK & CO., INC. Plaintiff and Counterclaim Defendant, v. RANBAXY INC., AND RANBAXY LABORATORIES LIMITED Defendants and Counterclaim Plaintiffs.	)	C.A. No. 07-229 (GMS)

MERCK'S ANSWERING CLAIM CONSTRUCTION BRIEF

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Dated: December 21, 2007

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The claim construction approach in Ranbaxy's opening brief runs counter to the proper approach to claim construction as dictated in *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005). Ranbaxy seeks to impose contorted restrictions on terms contrary to the actual scope of the claims as reflected in the specification and prosecution history. Ranbaxy also attempts to wholly re-write claim limitations and to re-define terms that have undisputed ordinary meanings. Ranbaxy's proposed constructions should be rejected.

I. Ranbaxy's Proposed Construction Of "A Compound" Should Be Rejected

Ranbaxy contends that the term "A compound" in claims 1 and 9 should be construed to "exclude[] a combination product containing the compound and a thienamycin-type compound." (D.I. 36, Brief on Claim Construction of Defendants Ranbaxy Inc. and Ranbaxy Laboratories Limited ("Ranbaxy Br.") at 14).[1] According to Ranbaxy, the '868 patent specification contains a "clear and unambiguous disclaimer" of claim coverage over the claimed compounds when they are used as part "of a combination product." (Ranbaxy Br. at 14). Ranbaxy argues that the Merck inventors, although seeking and obtaining claims to unique compounds, such as cilastatin, were disclaiming the preferred use of those unique compounds in combination with other ingredients.

A. Contrary To Ranbaxy's Assertion, There Was No Disclaimer Of Claim Coverage In The '868 Patent

Ranbaxy relies on two paragraphs from the specification of the '868 patent in support of its disclaimer argument. The first paragraph—which is the first paragraph in the section of the '868 patent entitled, "Methods of Using the Invention"—reads as follows:

> As mentioned above, the thienamycin-type compound is used in combination with the dipeptidase inhibitor. *The combination*

[1] The parties' claim construction positions are set forth in full in the Revised Joint Claim Construction Chart (D.I. 37, attached hereto as Exhibit A), which was filed December 11, 2007 to replace the Joint Claim Construction Chart (D.I. 33) filed December 3, 2007.

> *product is not part of this invention, but is claimed in a copending application*, Case 16174, U.S. Ser. No. 927,213, filed Jul. 24, 1978, now abandoned, and in Case 16174IA, U.S. Ser. No. 050,232, filed Jun. 22, 1979, now abandoned, and in Case 16174IB, filed concurrently herewith.

(Ranbaxy Br. at 14); (A1-21[2] at A5 ('868 Patent, col. 8, lns. 43-50) (italics by Ranbaxy)). Ranbaxy asserts that the italicized language in this paragraph constitutes a disclaimer of claim scope.

That paragraph, however, does not disclaim any coverage of the claimed compounds. The language "not part of this invention" means that the inventors on the '868 patent were not the inventors of the combination product and therefore could not present for examination claims ***requiring*** or reciting the two elements of the combination product. As Merck has previously explained, under black letter patent law, the addition of an unrecited element to an accused product does not take the combination outside the scope of the claims. *Atlas Powder Co. v. E.I. Du Pont de Nemours & Co.*, 750 F.2d 1569, 1580-81 (Fed. Cir. 1984) (holding claims to A + B + C covers combination of A + B + C + D). The inventors thus were not saying that the '868 patent claims directed towards particular compounds would not cover those same compounds when used in a combination product. In fact, the heading immediately preceding the paragraph Ranbaxy relies on is entitled "Methods of Using ***the Invention,***" thereby characterizing the combination as one method of using the claimed invention. (A1-21[3] at A5 ('868 Patent, col. 8, ln. 42)).

The paragraph quoted above also points out that the combination product "is claimed in a copending application." That statement also is not a disclaimer of claim coverage. The fact that another application claims the combination product does not mean that the

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[2] All citations to A numbers ("A__") refer to the Joint Appendix of Intrinsic and Extrinsic Evidence.

[3] Unless otherwise noted, all emphasis has been added.

compound claims in '868 patent do not cover the use of the claimed compounds in such a combination. *See Atlas Powder*, 750 F.2d at 1580-81; *In re Kaplan*, 789 F.2d 1574, 1577-78 (Fed. Cir. 1986).

A disclaimer of claim coverage requires "a clear disavowal of claim scope." *Nystrom v. Trex Co., Inc.*, 424 F.3d 1136, 1142 (Fed. Cir. 2005). Here, the '868 patent inventors said nothing to disclaim the normal scope of their compound claims, which would include coverage of the claimed compounds when used in a combination invented by another, such as the situation described in *Atlas Powder.*

In fact, in the second paragraph (which Ranbaxy quotes) of the "Methods of the Invention," the inventors explicitly advised the public that the claimed compounds are still the compounds "***of this invention***" even when they are combined with thienamycin-type compounds in a single pharmaceutical composition:

> The combination of the novel chemical inhibitors ***of this invention*** and the thienamycin class compound can be in the form of ***a pharmaceutical composition containing the two compounds*** in a pharmaceutically acceptable carrier. The two can be employed in amounts so that the weight ratio of the thienamycin class compound to inhibitor is 1:3 to 30:1, and preferably 1:1 to 5:1.

(A1-21 at A5 ('868 Patent, col. 8, lns. 51-58)). The inventors explicitly state in this same section that a "preferred dosage form known to applicants" was a single combination dose of a claimed compound with a thienamycin class compound. (A1-21 at A6 ('868 Patent, col. 9, lns. 3-14)). The use of the patent-law term of art "preferred" here indicates that this dosage form is a

preferred use of the invention.[4] Further, the inventors identify the "most preferred dosage regimen and level" as a specific combination product containing imipenem and cilastatin. (A1-21 at A6 ('868 Patent, col. 9, lns. 15-26)). Ranbaxy's attempt to exclude these preferred uses of the invention should be rejected. *See Pfizer, Inc. v. Teva Pharms. USA, Inc.*, 429 F.3d 1364, 1374 (Fed. Cir. 2005) ("A claim construction that excludes a preferred embodiment is rarely, if ever, correct.") (quoting *Sandisk Corp. v. Memorex Prods.*, 415 F.3d 1278, 1285 (Fed. Cir. 2005).

B. It Was Common Practice To Disclose Related Inventions From The Same Company Invented By Another Inventive Entity

Inventors often describe related inventions of others, especially where the two sets of inventors work for the same company. As the Federal Circuit's predecessor court explained,

> When [two] . . . inventions are related, as they are here, inventor A commonly discloses the invention of A&B in the course of describing his sole invention.

In re Land and Rogers, 368 F.2d 866, 879 (C.C.P.A. 1966) (quoting *Kaplan*, 789 F.2d at 1576). In *In re Kaplan*, in his solo patent application, Kaplan disclosed a related invention he had discovered along with a co-worker, Walker, because the Kaplan and Walker invention "was part of the 'best mode' of practicing Kaplan's catalytic process." 789 F.2d at 1575. Here, as noted above, the '868 patent inventors—Graham, Rogers and Kahan—described the combination with thienamycin-type compounds because it was a preferred embodiment of using the claimed compounds. Because the combination was invented by another inventive entity at Merck,

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[4] Ranbaxy cites four cases that "found a disclaimer of claim scope where the language was both clear and intentional." (Ranbaxy Br. at 17). Those cases are inapposite. None of the cases deal with the phrase "not part of the invention," nor do they involve disclaimers relating to the use of the invention with unclaimed elements in a combination product, as in *Atlas Powder*. All of Ranbaxy's cases involve limiting the claims to require an element found in the preferred embodiment or in all the embodiments disclosed in the patent specification. Here, the '868 patent specification affirmatively identifies the use of the claimed compound in the combination product as a preferred use of the invention.

namely Kahan and Kropp, the '868 patent inventors took pains to be clear that they did not invent the combination, stating, "[t]he combination product is not part of this invention." (A1-21 at A5 ('868 Patent, col. 8, lns. 45-46)).

Far from being a disclaimer of claim scope, the paragraphs Ranbaxy relies on do no more than advise the patent examiner that, although the '868 patent discloses the combination as a method of using the claimed compounds, the combination product is claimed in another copending application. Ranbaxy nevertheless accuses Merck of pursuing a "strategy" that included "failing to disclose the combination claims." (Ranbaxy Br. at 16). Ranbaxy's allegation is facially flawed—the inventors disclosed the combination claims in the very paragraphs Ranbaxy cites. (A1-21 at A5 ('868 Patent, col. 8, lns. 45-50)). Notably, the fact that an infringer would manufacture such a meritless charge only confirms the wisdom of expressly disclosing in the specification that the '868 inventors did not invent the combination and that the combination claims included in another application.

C. Under The Law In Effect in 1978-80, Merck Needed To File Two Separate Patent Applications

Ranbaxy suggests that there is something nefarious about filing two separate patent applications on related inventions. Ranbaxy asserts that Merck made "a clear and unequivocal decision…to simultaneously pursue — in separate patent applications — patent protection for dipeptidase inhibitors and a combination of a dipeptidase inhibitor with a thienamycin compound," as a part of a "strategy… to seek protection of cilastatin separately from a cilastatin-imipenem combination product in unrelated patents." (Ranbaxy Br. at 15). First, there is nothing nefarious, as noted above, in filing separate applications, one directed to new unique compounds and the other directed to another invention on the use of those compounds.

Second, contrary to Ranbaxy's contention, which it makes with no support, Merck did not ***choose*** to file two separate applications as a part of some unexplained, improper "strategy." Merck was ***required*** to file two applications under the law as it existed during the 1978-80 timeframe when the applications were filed.

The Federal Circuit has recognized that, "[p]rior to the 1984 [Patent] Act, inventors could not apply jointly unless each made an inventive contribution to the subject matter of every claim." *In re Berg*, 140 F.3d 1428, 1433 at n. 4 (Fed. Cir. 1998); *Kaplan*, 789 F.2d at 1576, n. 1. Here, different inventive entities invented the claimed compounds of the '868 patent (Graham, Rogers and Kahan) and the claimed combinations of the '208 patent (Kahan and Kropp). Thus, neither inventive entity contributed to the conception of both inventions, and Merck could not include claims reciting both inventions in one application. As a result, Merck filed two separate patent applications prior to the 1984 Act.

II. Contrary To Ranbaxy's Assertion, Claim 19 Recites An "Acid"— Not A "Free Acid"

Ranbaxy contends that the "heptenoic acid" compound in claim 19 should be construed so as to be limited to the free acid form. (Ranbaxy Br. at 29-31). There is no dispute that the term "free acid" in the '868 patent refers to a compound where R^1 is hydrogen. The issue is whether the term "acid" means the same thing as "free acid" or is instead a general term that refers to all forms of acid compounds identified in the '868 patent specification, such as "sodium…heptenoic acid" and "heptenoic acid sodium salt."

In support of its construction, Ranbaxy contends that claim 19 "specifies that the claimed compound is the ***free*** heptenoic acid, in which R^1 is hydrogen." (Ranbaxy Br. at 29). Claim 19 specifies nothing of the sort. It in fact does not recite a "***free*** acid" at all, nor does it specify that R^1 is hydrogen. Rather, claim 19 simply recites an "acid," stating "[t]he compound

of claim 9 which is 7-(L-2-amino-2-carboxyethylthio)-2-(2,2-dimethylcyclopropanecarboxamido)-2-***heptenoic acid***." (A1-21 at A20 ('868 Patent, col. 40, lns. 21-23)). Ranbaxy's attempt to limit that term to a "free acid" is improper.

A. The '868 Patent Specification Does Not Support Ranbaxy's Proposed Construction—It in Fact Squarely Supports Merck's Construction

Ranbaxy asserts that the '868 patent specification supports its contention that the "heptenoic acid" in claim 19 refers only to the free acid. The portion of the specification cited by Ranbaxy actually supports the opposite conclusion. In addition, other portions of the specification further confirm that Ranbaxy's contention is wrong.

Ranbaxy contends that its construction "is supported by the clear and unambiguous definition provided in the '868 patent specification," quoting the following passage:

> Although these compounds of Formula I, ***when R1 is H***, are described and named as the ***free acids***, it will be apparent to one skilled in the art that various pharmaceutically acceptable derivatives such as alkali and alkaline earth metal, ammonium, or amine salts, or the like can be employed as equivalents thereto. Salts such as the sodium, potassium, calcium, or tetramethylammonium ***salts*** are suitable.

(Ranbaxy Br. at 29-30; A1-21 at A4 ('868 Patent, col. 5, lns. 11-19)). However, this passage distinguishes "free acid" from salts, not "acid" from salts. As Ranbaxy concedes in its brief, "[t]he specification clearly and unambiguously distinguishes the ***free acid*** from ***other derivatives*** of compounds…. " (Ranbaxy Br. at 29). Again, claim 19 does not recite a "free acid" but an "acid." Thus, Ranbaxy's reliance on the above passage does not support its contention in any way.

Notably, the preceding two columns of the '868 patent specification refer to numerous "acids." Nevertheless, the '868 patent specification does not state that these "acid"

compounds are all compounds wherein ***R1 is H,*** and therefore free acids. Rather, column 5 of the '868 patent implies that these acids include the free acids as well as other forms of the compounds. The passage reads: "these compounds of Formula I, ***when R1 is H*** are described and named as the ***free acids."*** (A1-21 at A4 ('868 Patent, col. 5, lns. 11-12)). The passage then goes on to describe the other forms of the compounds.

The '868 patent specification's use of the word "acid" in a broad sense is similar to that in *Merck & Co. v. Teva Pharms. USA, Inc*., 347 F.3d 1367 (Fed. Cir. 2003) (affirming district court decision at 228 F. Supp. 2d 480, 489 (D. Del. 2002)). In that case, this Court and the Federal Circuit found that in the patent at issue, Merck used "the word 'acid' to encompass the sodium salt [form]. . . ." *Merck*, 347 F.3d at 1371. In reaching this conclusion, the Federal Circuit noted that the patent specification at issue in *Merck v. Teva*:

> refer[red] to formulation of various biphosphonic ***acids for administration 'as the sodium salt,'*** 'in the salt form,' 'in the form of Na salt,' and as '4-amino-1-hydroxybutan-1,1-biphosphonic acid, sodium salt.'

Merck, 347 F.3d at 1370. The '868 patent specification does the same. The '868 patent specification describes the ***administration of the claimed heptenoic acid*** of claim 19 as a "***sodium salt***":

> The most preferred dosage regimen and level is the combination of crystalline N-formimidoyl thienamycin and the other being the crystalline form of 7-(L-amino-2-carboxyethylthio)-2-(2,2-dimethylcyclopropanecarboxamido)-2-***heptenoic acid co-administered*** in a sterile aqueous IV injection form (***sodium salt***).

(A1-21 at A6 ('868 Patent, col. 9, lns. 15-25); (*see also* col. 9, lns. 3-14, describing the ***co-administration*** of Z-2-(2,2-dimethylcyclopropanecarboxamido)-2-***octenoic acid*** with N-formimidoyl thienamycin ***as a sodium salt***)). Thus, the '868 patent specification plainly uses the term "acid" to encompass its salt form.

Further, in construing "acid" to include salt forms, the Federal Circuit in *Merck v. Teva* noted that the patent at issue referred to acids in their sodium salt forms, such as "4-amino-1-hydroxybutan-1, 1-diphosphonic ***acid, sodium salt***." *Merck*, 347 F.3d at 1370. Similarly, here, the '868 patent specification refers to acids in their sodium salt forms in exactly the same manner. (*See, e.g*, A1-21 at A14, A19 ('868 Patent, col. 27, lns. 18-19, "(+)-Z-2-(2,2-Dimethylcyclopropanecarbonylamino)-2-octenoic ***acid, sodium salt***."); (col. 37, lns. 59-62, "Z-2-(2,2-Dimethylcyclopropanecarboxamido)-7-sulfo-2-heptenoic ***acid sodium salt***" and "Z-2-(2,2-Dimethylcyclopropanecarboxamido)-8-sulfo-2-octenoic ***acid sodium salt***")). Accordingly, based on the '868 patent specification and controlling Federal Circuit precedent, the heptenoic acid compound in claim 19 is not limited to the free acid form, as Ranbaxy contends.

B. Ranbaxy's Reliance On *Pfizer* Is Misplaced

Ranbaxy relies on *Pfizer Inc. v. Ranbaxy Labs. Ltd*., 457 F.3d 1284 (Fed. Cir. 2006), for its argument that the word "acid" in claim 19 should be limited to a free acid. (Ranbaxy Br. at 30-31). Ranbaxy's reliance is misplaced. In *Pfizer*, the construction of the word "acid" was not at issue in the case. There was no dispute that the language of the claims made clear that, for the purpose of those claims, the term "acid" did not include the salt forms of the compound. *Pfizer, Inc. v. Ranbaxy Labs. Ltd.*, 405 F.Supp. 2d 495, 507-509 (D. Del. 2005) (reversed-in-part by 457 F.3d 1284 (Fed. Cir. 2006)). Indeed, the Federal Circuit expressly noted that the *Pfizer* case presented a situation different from the *Merck v. Teva* case just discussed. *Pfizer*, 457 F.3d at 1291 n. 6.

Specifically, claim 1 in the *Pfizer* patent recited three distinct forms of the atorvastatin compound at issue, (1) atorvastatin ***acid***; or (2) atorvastatin lactone (the "carboxamide"); or (3) pharmaceutically acceptable ***salts*** thereof. Claim 1 recited:

> [R-(R *,R*)]-2-(4-fluorophenyl)-β, δ-dihydroxy-5-(1-methylethyl)-3-phenyl-4-[(phenylamino)-carbonyl]-1H-pyrrole-1-heptanoic ***acid*** **or** (2R-trans)-5-(4-fluorophenyl)-2-(1-methylethyl)-N,4-diphenyl-1-[2-(tetrahydro-4-hydroxy-6-oxo-2H-pyran-2-yl)ethyl]-1H-pyrrole-3-***carboxamide;*** **or** pharmaceutically acceptable ***salts*** thereof.

Pfizer, 457 F.3d at 1288. Thus, claim 1 itself distinguished the "acid" compound from the salt by the use of the disjunctive term "or" in the manner in which the claim is drafted. When dependent claim 2 used the word "acid" it was undisputed that this claim selected the first of the three categories in claim 1—the acid—and excluded the other two—the lactone form and the salt forms. *Id.*

Ranbaxy argues that independent claim 9 in the '868 patent is like claim 1 in the *Pfizer* patent. According to Ranbaxy, claim 9 allegedly "***recited*** (1) an acid and (2) pharmaceutically acceptable salts," and that dependent claim 19 then selected the acid form. Ranbaxy is wrong. Claim 9 does not recite the word "acid" at all. (A1-21 at A20 ('868 Patent, col. 39, lns. 19-36)). For the R1 group, claim 9 recites: "R^1 is hydrogen, loweralkyl of 1-6 carbon atoms, dialkylaminoalkyl, or a pharmaceutically acceptable cation." (A1-21 at A20 ('868 Patent, col. 39, lns. 30-32)). There is nothing in claims 9 or 19 that would suggest that the word "acid" in claim 19 does not include all of the R^1 forms, just as it was broadly used in the '868 patent specification.[5] (A1-21 at A20 ('868 Patent, col. 40, lns. 21-23)).

The situation here also differs from that in *Pfizer* where independent claim 1 simply recited a single compound in three alternative forms, described as an acid, a lactone and

[5] Ranbaxy proposes a definition for the R^1 in claim 9 in an improper attempt to re-write it to make it look more like the claim at issue in *Pfizer,* but even that just points out a flaw in its argument. Ranbaxy argues: "R1 defines three mutually exclusive subgenera: (1) ***a free acid*** form in which R^1 is hydrogen, (2) ***ester forms*** … , and (3) ***salt forms*** in which R^1 is a pharmaceutically acceptable cation." (Ranbaxy Br. at 27). Ranbaxy's proposed re-write only uses the term "a free acid," not the term "an acid," in the alternative with esters and salts. Thus, Ranbaxy's proposed re-write says nothing about whether the word "acid," unlike "free acid," encompasses all three forms of the compound.

salts. The only possible purpose of dependent claim 2 in the *Pfizer* patent was to narrow claim 1 by selecting one of the forms of that single compound. *Pfizer*, 457 F.3d at 1291. Here, however, the purpose of claim 19 was not to select one of the R^1 groups, but rather to select particular R^2 and R^3 groups from the genus of independent claim 9. Claim 9 recites a genus of multiple compounds, with various choices to select for the R^1, R^2 and R^3 groups. From that genus, claim 19 selects a particular compound with respect the R^2 and R^3 groups, specifically the R^2 group 2,2-dimethylcyclopropyl and the R^3 group as a moiety that has a 2-amino-2-carboxyethylthio. Claim 19, however, does select an R^1 group from the list specified in claim 9.

Instead, claim 19 uses the broad term "heptenoic acid." As pointed out above, the patent specification uses "heptenoic acid" in the broad sense to refer to multiple forms, including the salt forms. For example, the patent refers to the compound of example 19A as "Sodium …. heptenoic acid." (A1-21 at A17 ('868 Patent, col. 34, lns. 11-13 (Example 19A), "***Sodium*** Z-7-(L-amino-2-Carboxethylthio)-2-(2,2-dimethylcyclopropane carboxamido)-2-heptenoic ***acid***.")). Thus, the heptenoic acid recited in claim 19 encompasses the salt forms of the compound.

C. Ranbaxy's Construction Of The Term "The Sodium, Potassium, Calcium Or Magnesium Salt Form" In Claim 20 Is Without Merit

A related issue to the interpretation of the "heptenoic acid" in claim 19 involves claim 20. Claim 20 recites "[t]he compound of claim 19 in ***the sodium, potassium, calcium or magnesium salt form***." (A1-21 at A20 ('868 Patent, col. 40, lns. 24-25)). Ranbaxy asserts that claim 20 is invalid based on its interpretation of claim 19. Ranbaxy also asserts that the court should further construe claim 20 to additionally include the requirement that it "***exclud[e] the free acid form***." (Ranbaxy Br. at 31). That additional language, however, is found nowhere in the claim. Ranbaxy's attempt to re-word the plain claim language should thus be rejected.

III. Ranbaxy's Construction Of The Term "Pharmaceutically Acceptable Cation" And The Definition Of R^1 In Claims 1 And 9 Should Be Rejected

Ranbaxy argues that the term "pharmaceutically acceptable cation" should be construed to mean "***[a]ny cation*** useful in the salt form of the claimed pharmaceutical compound." (Ranbaxy Br. at 22). Ranbaxy argues that its construction is proper because the term "pharmaceutically acceptable cation" "is not limited to the specific examples of pharmaceutically acceptable derivatives listed in the '868 patent." (*Id.*). Ranbaxy misses the point. Ranbaxy's construction impermissibly reads out the express limitation that the "cation" must be "pharmaceutically acceptable." (D.I. 38, Merck's Opening Claim Construction Brief ("Merck Br.") at 20-21). That is obviously improper.

Ranbaxy also attempts to improperly re-write the definitions of the R^1 groups in claims 1 and 9. Although those claims expressly define the R^1 group, Ranbaxy proposes that those definitions be re-worded. (Ranbaxy Br. at 21-22, 27-29). As discussed above, Ranbaxy proposes the constructions that define the R^1 groups in terms of "mutually exclusive subgenera," including one subgenera that is a free acid form and at least another subgenera that is a salt forms.

Ranbaxy's constructions are unnecessary. With the exception of the term "pharmaceutically acceptable cation," the parties do not dispute the meaning of any term in the definition of R^1 recited in the claims. Accordingly, the definitions of the R^1 group found in the claims themselves should not be re-worded or further construed. Moreover, Ranbaxy's constructions again use words found nowhere in the claim language, such as "mutually exclusive subgenera," "free acid form," "salt form," and "ester forms." They also inject technical issues into the case, such as whether the R^1 group defines "mutually exclusive subgenera" in all instances. Ranbaxy's construction should be rejected.

IV. Ranbaxy's Proposed Construction Of "Alkyl" In Certain Chemical Moieties Should Be Rejected

Ranbaxy contends that the Court should construe the meaning of certain composite chemical terms in claim 1, such as trialkylammonium.[6] Ranbaxy, however, does not actually attempt to construe any of those particular composite terms. Instead, Ranbaxy proposes a definition of "alkyl" to be used in each composite term:

> Each alkyl group in [… the composite chemical terms] includes a linear, branched, or cyclic alkyl group without limitation as to number of carbon atoms.

(Ranbaxy Br. at 10).

Ranbaxy's construction is fundamentally flawed, as it attempts to construe only a portion of each composite term—"alkyl"—rather than construe those composite terms as a whole. Ranbaxy's contention that "alkyl . . . is not qualified or modified" by other claim language is plainly wrong. (Ranbaxy Br. at 11). The term "alkyl" is both "qualified" and "modified" here because it is incorporated into larger composite chemical terms, for example "trialkylammonium." A person of ordinary skill would understand the meaning of those composite terms and, in particular, recognize that they do not refer to compounds with alkyls of unlimited length.[7] (Merck Br. at 22-24). Accordingly, Ranbaxy's attempt to construe "alkyl" in the abstract, without consideration of the ordinary meaning of the composite terms in which it appears, should be rejected.

Moreover, even if the meaning of the composite terms as a whole were set aside, Ranbaxy has no support for its construction. Ranbaxy invokes the "ordinary … and common

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[6] The other composite terms include quartenary hydroxyalkylammonium, phosphonylalkylamino, hydroxyalkylamino, alkylamidino, N,N-dialkylguanidino, alkylcarbonylokxy, and alkoxycarbonyl.

[7] Merck does not dispute that the alkyl substituents on the chemical groups at issue here may be linear, branched, or cyclic.

meaning," of "alkyl," but offers no evidence showing that the ordinary meaning matches Ranbaxy's construction. Certainly, Ranbaxy has not presented any evidence that the ordinary meaning of "alkyl" is "without limitation as to number of carbon atoms." (Ranbaxy Br. at 10-11).

V. Ranbaxy's Proposed Constructions Of "X" And "Y" In Claim 1 And "R2" In Claim 22 Should Be Rejected

Ranbaxy contends that the Court should construe the groups "X" and "Y" in claim 1 and "R^2" in claim 22 to list certain examples of chemical groups that would be encompassed by the definitions of those groups in the claims. Ranbaxy attempts to re-write properly defined genus claim terms, by changing them to recite lists of various examples of compounds included in the genus as defined in the claims. Ranbaxy apparently then will later argue that the claim is invalid because some of those examples are allegedly not recited in the '868 patent specification. As Ranbaxy states in its brief, with respect to "X,"

> It is Ranbaxy's position that this scope is not supported by the written description of the specification as required by 35 U.S.C. 112, first paragraph, and that Claim 1 is therefore invalid for lack of support.

(Ranbaxy Br. at 7). Ranbaxy's brief makes the identical contention for "Y" and "R^2" in claim 22.

Ranbaxy's proposed constructions of "X," "Y," and "R^2" wrongly imply that the '868 patent must disclose Ranbaxy's examples of compounds within the genus in order to satisfy the written description requirement. The groups do not recite specific examples. Claim 1, for instance, recites group "X," which recites various characteristics shared by the genus of related chemical groups covered by "X." Accordingly, the issue for Ranbaxy's written description defense is whether the disclosure in the original application adequately disclosed the genus "X." *Bilstad v. Wakalopulos*, 386 F.3d 1116, 1123 (Fed. Cir. 2004) ("The question requires

consideration of whether the… disclosure, as filed, reasonably conveys to a person skilled in the art that the inventor had possession of the claimed subject matter at the time of the earlier filing date.").

The issue is not whether the specification identified each of the examples spelled out by Ranbaxy. A specification need not disclose every example covered by a genus to satisfy the written description requirement. *In re Herschler*, 591 F.2d 693, 700-701 (C.C.P.A. 1979) ("The claimed subject matter need not be described *in haec verba* to satisfy the description requirement."). Indeed, "disclosure of a single species within a genus may be enough support for a claim directed to the genus." *Bilstad*, 386 F.3d at 1124; *Herschler*, 591 F.2d at 700-701. Thus, Ranbaxy's proposed construction of "X" mis-frames the written description issue by suggesting that the '868 patent must separately disclose each example on Ranbaxy's list.

Moreover, Ranbaxy's lists of examples are misleadingly incomplete. Ranbaxy itself admits with respect to all three groups that "R^2 is more broadly defined" than the examples on Ranbaxy's lists. (Ranbaxy Br. at 6). Ranbaxy contends that each group "includes at least the following…." (*Id.*). Ranbaxy omits a number of examples of the claimed subject matter. For instance, Ranbaxy's proposed construction of "X" does not include a linear alkyl group of three carbons substituted with a cycloalkyl group of six carbons, as disclosed in the specification in Table I, at item 21. (A1-21 at A7.1 ('868 Patent, col. 13-col. 14)). Also, Ranbaxy's construction does not reflect the fact that the disclosure of a genus can provide support for a claim to a related genus. *In re Wertheim*, 541 F.2d 257, 264-265 (C.C.P.A. 1976). Here, the '868 patent discloses that R^2, which recites "X," can be "a straight, branched or cyclic hydrocarbon radical of 3-10 carbon atoms." (A1-21 at A2 ('868 Patent, col. 2, lns. 28-29)). Thus, the '868 patent could

adequately describe the genus of "X" without disclosing ***any*** of the examples listed in Ranbaxy's proposed construction.

Ranbaxy contends that its proposed constructions are necessary to "preclude[]" Merck "from later asserting any narrower scope" of "X," "Y," and "R^2." (Ranbaxy Br. at 7, 9, 12). Merck, however, does not seek a "narrower" construction of the groups at all. Rather, these groups need no construction, as they are precisely defined genus groups.

VI. Ranbaxy's Proposed Constructions Relating To Isomers And Enantiomers Should Be Rejected

Ranbaxy offers several proposed constructions relating to isomers and enantiomers of the claimed compounds and compositions containing those compounds, including mixtures of those compounds. This issue relates to Ranbaxy's proposed constructions for: (a) the structural formula in claims 1 and 9; and (b) the term "2,2-dimethylcyclopropyl" in claims 2 and 9 and the "2,2-dimethylcyclopropanecarboxamido" group in the compound recited in claim 19 (which is also incorporated into dependent claim 20).

There is no dispute that a person of ordinary skill would understand that the recited structure includes, for example, the compounds in the S configuration and compounds in the R configuration. However, while the claims would cover mixtures and racemates of the claimed compounds in the S configuration and the R configuration, the claims themselves recite compounds, not mixtures or racemates.

VII. Contrary To Ranbaxy's Assertion, The Term "Said One To Fifteen Carbon Alkyl" In Claim 1 Should Be Corrected To Read "Said Two To Fifteen Carbon Alkyl"

Ranbaxy asserts that the Court should not correct the typographical error in the claim term "said one to fifteen carbon alkyl." Ranbaxy asserts that claim 1 presents two separate and inconsistent definitions of group R^3. Ranbaxy also asserts that the Federal Circuit case law does not permit the type of correction sought here. Finally, Ranbaxy argues that the proposed

correction would not be supported by the '868 patent specification. Ranbaxy is wrong on all three points.

A. Claim 1 Does Not Recite Two Definitions Of R^3

Ranbaxy erroneously argues that claim 1 contains two definitions of the R^3 group. In particular, Ranbaxy states:

> Claim 1 contains inconsistent definitions of alkyl groups represented by substituent R^3 in the general formula, and ***recites both that***:
>
> ***R^3 is*** "unsubstituted or substituted two to fifteen carbon alkyl" and
>
> ***R^3 is*** "said one to fifteen carbon alkyl."

(Ranbaxy Br. at 23). Claim 1 does not state that "R^3 is 'said one to fifteen carbon alkyl.'" Claim 1 provides only one definition of the R^3 group, and that limits R^3 to two to fifteen carbon alkyls.

Claim 1 recites, in relevant part:

> ***R^3 is unsubstituted or substituted two to fifteen carbon alkyl*** wherein said substituent is halogen, and wherein a non-terminal methylene can be replaced by oxygen, sulfur or SO_2 and wherein the terminal carbon of said alkyl can be substituted by a moiety selected from the group consisting of [list of moieties], with the ***proviso*** that no more than six hydrogens of ***said one to fifteen carbon alkyl*** can be substituted by halogen . . . ."

(A1-21 at A19 ('868 Patent, col. 38, lns. 42-61)). The R^3 group is defined as an "unsubstituted or substituted two to fifteen carbon alkyl." That is the only definition of the R^3 group in the claim. As a result, the R^3 group cannot contain one carbon.

The term "***said*** one to fifteen carbon alkyl" is a proviso relating to a particular aspect of that earlier definition—namely, how many halogen atoms may be substituted on to the two to fifteen carbon alkyl. By using the word "***said***," that term plainly refers to the "two to fifteen carbon alkyl" and cannot be a second definition of R^3. *See Intamin, Ltd. v. Magnetar*

Techs., Corp., 483 F.3d 1328, 1333 (Fed. Cir. 2007) ("The use of the word 'said' in a claim refers to an earlier use of the term in the claim.").[8]

Given the plain language of the definition of R^3 and the use of the word "said" in the proviso, the only possible conclusion is that the term "said one to fifteen carbon alkyl" in the proviso is a typographical error and that it should have recited "said two to fifteen carbon alkyl." (Merck Br. at 28-31). The typographical error, and the necessary correction, are both apparent from the language of the claim itself.

As to the prosecution history, Ranbaxy asserts that the amendment to limit the R^3 group to "R^3 is unsubstituted or substituted two to fifteen carbon alkyl" was unexplained. Ranbaxy also asserts that the Examiner made a "partial amendment" and "did not explain why the remaining, broader definition of R^3 was retained." Ranbaxy wholly ignores the record of the prosecution history on this point. The examiner explicitly stated that she intended to amend the claim "to ***exclude compounds wherein 'R^3' is 1 carbon alkyl***." (A841 (U.S. Appln. Serial No. 07/839,725, Examiner Interview Summary Record dated March 26, 1992)). Thus, the prosecution history confirms that the phrase "said one to fifteen carbon alkyl" contains a typographical error. Plainly, the examiner and the applicant simply forgot to change the proviso's recitation of "said one to fifteen carbon alkyl" in the claim to "said two to fifteen carbon alkyl."

---

[8] Moreover, even if claim 1 had two definitions of the R^3 group, one being "two to fifteen carbon alkyl" and the other being "one to fifteen carbon alkyl," claim 1 would still not be indefinite. In that circumstance, both limitations would need to be satisfied to infringe the claim. An accused compound with a R^3 group consisting of a one carbon alkyl would not meet both limitations; therefore, that compound would not infringe. Merck does not fully address this invalidity argument of Ranbaxy, as the present briefing relates to claim construction only.

Under these circumstances, this Court can correct the typographical error. The Federal Circuit has held that district courts may correct errors in a patent where "(1) the correction is not subject to reasonable debate based on consideration of the claim language and the specification and (2) the prosecution history does not suggest a different interpretation of the claims." *Novo Indus., L.P. v. Micro Molds Corp*., 350 F.3d 1348, 1357 (Fed. Cir. 2003); *see also Hoffer v. Microsoft Corp.*, 405 F.3d 1326, 1331 (Fed. Cir. 2005) ("When a harmless error in a patent is not subject to reasonable debate, it can be corrected by the court . . . ."). Here, the correction sought is not subject to reasonable debate, as discussed above. Nor does the prosecution history suggest a different conclusion. (Merck Br. at 28-31) Accordingly, this Court may and should make the correction.[9]

B. The Cases Cited By Ranbaxy Do Not Apply

Ranbaxy cites *Chef America, Inc. v. Lamb-Weston, Inc*., 358 F.3d 1371, 1374 (Fed. Cir. 2004), for the proposition that "[e]ven where the plain language of a claim is nonsensical, and this fact is apparent from review of the specification, 'courts may not redraft claims, whether to make them operable or to sustain their validity.'" (Ranbaxy Br. at 27). That case had nothing to do with the correction of errors in a patent pursuant to the Federal Circuit's holding in *Novo Indus.*, but rather, related to claim construction issues. Indeed, the court in *Chef America* noted:

> Chef America does not contend that the patentees' use of "to" rather than "at" was a draftsman's mistake. ***The patentees made no attempt to have such an error corrected***, either by obtaining a certificate of correction from the Patent and Trademark Office pursuant to 35 U.S.C. § 255, or ***by action of the district court. Cf.***

[9] Ranbaxy's criticism that Merck never applied for a certificate of correction to correct the error is legally irrelevant. There is no need for Merck to have done so. As set forth in *Novo Industries*, courts are allowed to correct errors in a patent in circumstances such as those here even though "***no certificate of correction has been issued***." 350 F.3d at 1331, 1355-56.

> ***Novo Indus. v. Micro Molds Corp.***, 350 F.3d 1348 (Fed. Cir. 2003). To the contrary they argue only that "to" should be construed to mean "at" because otherwise the patented process could not perform the function the patentees intended.

Chef America, 358 F.3d at 1375.

Moreover, Ranbaxy is wrong in saying that the "plain language of a claim is nonsensical, and this fact is apparent from review of the specification." To the contrary, the plain language of the claim—related to heating cookie dough to a high temperature—made sense as written. *Id.* at 1373 ("These are ordinary, simple English words whose meaning is clear and unquestionable."). Moreover, the specification did not suggest that the claim limitation was nonsensical. The Federal Circuit noted that, consistent with the claims, one baking process in the specification involved "quickly heating [the batter] to a temperature in the range of about 400 degrees F to 850 degrees F." *Id.* at 1374.

The nonsensical nature of the claim limitation did not become apparent from anything written in the claims, the specification or the prosecution history, but rather from extrinsic evidence that those high temperatures would result in an unusable product. *Id.* at 1374-75. Thus, the patentee in *Chef America* could not satisfy the requirements of *Novo Indus.* nor did it even try to do so.

Similarly, Ranbaxy's reliance on *Allen Eng'g Corp. v. Bartell Indus., Inc.*, 299 F.3d 1336 (Fed. Cir. 2002), for the proposition that "it is of no moment that the contradiction is obvious: semantic indefiniteness of claims is not rendered unobjectionable simply because it could have been corrected" is without merit. (Ranbaxy Br. at 27). That case too did ***not*** involve a situation where the patentee sought to correct an error in a patent, either through a certificate of correction or pursuant to the Federal Circuit's holding in *Novo Indus. v. Micro Molds Corp. Allen Eng'g*, 299 F.3d at 1349.

C. Merck's Requested Correction Has Written Description Support In The '868 Patent

Ranbaxy also argues that this Court should not correct the term "said one to fifteen carbon alkyl" because there is no written description support for the R^3 group to be a "two to fifteen carbon alkyl." (Ranbaxy Br. at 23-25). Ranbaxy is wrong.

First, the examiner already found that the range of "two to fifteen carbon alkyl" is supported by the '868 patent specification when she changed the definition of the R^3 group to "one to fifteen carbon alkyl" in claim 1 to "two to fifteen carbon alkyl." (Merck Br. at 30-31). The Examiner's finding was correct.

Ranbaxy concedes that the '868 patent specification supports R^3 having between "one to fifteen carbon alkyl." (Ranbaxy Br. at 23). There is also no dispute that the '868 patent specification recites multiple examples of compounds in which ***R^3 is two carbons***. (A1-21 at A7-9 ('868 Patent, cols. 11, 13, 15, 17 (Table I at Items 1, 4, 33, 45, 53))). Accordingly, the narrower range of R^3 having between "two to fifteen carbon alkyl" involves nothing more than changing the lower limit of the broad range to match examples disclosed in the specification.

Courts have found that narrow numerical claim ranges are supported by broader ranges in the specification when the specification also discloses examples to the change the lower limit of the claim range. *See, e.g., Wertheim*, 541 F.2d at 264-65. For example, in *In re Wertheim*, the specification disclosed a broad range of 25-60%, and an example of a specific embodiment of 36%. The court found that the claimed range of 35-60% was fully supported by the broad range and that example. *Id.* at 265. Likewise, here, the '868 patent specification

disclosed both the upper and lower limits of the narrower range. Accordingly, the '868 patent specification supports the range of "two to fifteen carbon alkyl."[10]

[10] Ranbaxy's reliance on *Scriptgen Pharms., Inc. v. 3-Dimensional Pharms., Inc*. for the proposition that the '868 patent specification does not support the range of "two to fifteen carbon alkyl" is without merit. That case did not involve the issue of written description at all; rather, it related to whether a limitation from the specification should be read into the claims. *See* 79 F. Supp. 2d 409, 418-19 (D. Del. 1999).

CONCLUSION

For the reasons stated above, Merck respectfully requests that the Court adopt Merck's proposed claim constructions.

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Dated: December 21, 2007
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CERTIFICATE OF SERVICE

I hereby certify that on December 21, 2007, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF which will send electronic notification of such filing to the following:

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Additionally, I hereby certify that true and correct copies of the foregoing were caused to be served on December 21, 2007 upon the following individuals in the manner indicated:

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TAB A

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MERCK & CO., INC., Plaintiff and Counterclaim Defendant, v. RANBAXY INC., and RANBAXY LABORATORIES LIMITED, Defendants and Counterclaim Plaintiffs.	)	C.A. No. 07-229 (GMS)

PARTIES' REVISED JOINT CLAIM CONSTRUCTION CHART

Attached hereto as Exhibit A is the parties' Revised Joint Claim Construction Chart for U.S. Patent No. 5,147,868. This revises the parties' Joint Claim Construction Chart (D.I. 33) filed on December 3, 2007.

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EXHIBIT A

MERCK & CO., INC. v. RANBAXY INC. AND RANBAXY LABS. INC.
CIVIL ACTION NO. 07-229 (GMS) (D. DEL.)

REVISED JOINT CLAIM CONSTRUCTION CHART

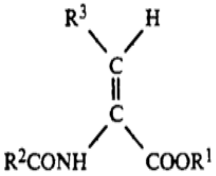
Agreed Construction[1]

Claim Limitation	Claim at Issue	Construction
witho	22	with

Asserted claims: 1, 2, 9, 19, 20, 22, 23, 24

U.S. Patent No. 5,147,868 Claim Limitation	Claims at Issue	MERCK		RANBAXY	
		CONSTRUCTION	INTRINSIC EVIDENCE	CONSTRUCTION	INTRINSIC EVIDENCE
"A compound"	1, 9	"A substance composed of atoms or ions of two or more elements in chemical combination."	'868 patent, Abstract, col. 1, lns. 20-43; col. 5, ln. 20 - col. 10, ln. 46; col. 19, lns. 35-67; col. 20, ln. 35 - col. 21, ln. 43; col. 38, ln. 9 - col. 40, ln. 40 (Claims 1-24);	"A compound" excludes a combination product containing the compound and a thienamycin-type compound.	'868 patent, 8:43-51 and applications/patents cited therein and stemming therefrom; '868 patent, 5:20-9:45.

[1] The parties jointly and respectfully submit that, if the Court deems it appropriate, the Court include the agreed-upon claim construction in its Claim Construction Order, or in the alternative, that this agreed upon construction is a binding stipulation between the parties.

U.S. Patent No. 5,147,868 Claim Limitation	Claims at Issue	MERCK		RANBAXY	
		CONSTRUCTION	INTRINSIC EVIDENCE	CONSTRUCTION	INTRINSIC EVIDENCE
			U.S. Appl. Ser. No. 06/748,300 (6/5/86 Communication to the Examiner under 37 C.F.R. §1.56 enclosing Abstract and accompanying information from the ICAAC, Sept. 22-24, 1980).		
	1	This formula needs no construction. The formula defines the structure illustrated, which shows the Z-stereoconfiguration.	'868 Patent, col. 1, ln. 45 - col. 5, ln. 11; A. Srinavasan et al. *Tetrahedron Lett.*, 891 (1976).	The formula includes racemates, mixtures, isomers, and enantiomers of the free acid form and salt forms of the compound, with the exception of the E-stereoisomer form.	'868 patent, 2:18-5:10, Table I, cols. 11-20 and Examples 1-23, Claims 1, 9, 19 and 20; Application Ser. No. 06/465,577: Office Action dated February 24, 1984; Response under 37 C.F.R. §1.111 dated July 7, 1984; Office Action dated December 4, 1984; Application Ser. No. 06/748,300, Office Action of February 24, 1985, Amendment dated

U.S. Patent No. 5,147,868 Claim Limitation	Claims at Issue	MERCK		RANBAXY	
		CONSTRUCTION	INTRINSIC EVIDENCE	CONSTRUCTION	INTRINSIC EVIDENCE
					May 15, 1986, Communication to the Examiner under 37 C.F.R. §1.56, dated June 5, 1986; Ashton, *et al.* Abstract no. 271 and "poster session," (ICAAC) Sept. 22-24, 1980; Application Ser. No. 06/878,391: Office Action dated Nov. 6, 1986; Amendment under 37 C.F.R. §1.116 received April 6, 1987; J. E. Blackwood et al., *J. Am. Chem. Soc.*, 90, p. 509 (1968); A. Srinavasan et al. *Tetrahedron Lett.*, 891 (1976).
pharmaceutically acceptable cation	1, 9	This term means "a cation acceptable for pharmaceutical use in connection with the	'868 patent, col. 5, lns. 12-18; col. 34, lns. 10-68; col. col. 38, lns. 9-66 (Claim 1); col. 39, lns.	Any cation useful in the salt form of the claimed pharmaceutical compound.	not defined (*cf.* '868 patent, 1:60-5:19, cols. 11-20 (Table 1).

U.S. Patent No. 5,147,868 Claim Limitation	Claims at Issue	MERCK		RANBAXY	
		CONSTRUCTION	INTRINSIC EVIDENCE	CONSTRUCTION	INTRINSIC EVIDENCE
		claimed compounds."	18-36 (Claim 9); U.S. Appl. Ser. No. 06/188,178 (9/17/80 Application).		
R1 is hydrogen or a pharmaceutically acceptable cation;	1	This phrase as a whole needs no construction. The phrase "R1 is hydrogen" needs no claim construction. The term "pharmaceutically acceptable cation" is defined by the parties above.	'868 patent, col. 1, ln. 45 - col. 2, ln. 45; col. 5, lns. 12-18; col. 38, lns. 10-66 (Claim 1).	R1 defines two mutually exclusive subgenera: (1) a free acid form in which R1 is hydrogen, and (2) salt forms in which R1 is a pharmaceutically acceptable cation.	'868 patent 1:60-5:6, 5:11-19; 2:18-5:10, Table I, cols. 11-20 and Examples 1-23, Claims 1, 9, 19 and 20.
X	1	"X" needs no construction. The claim defines "X" to mean: "unsubstituted or substituted branched or linear alkyl of three to	'868 patent, col. 1, ln. 45 - col. 5, ln. 10; col. 10, ln. 45 - col. 38, ln. 8; col. 38, lns. 9-66 (Claim 1).	X includes at least: a branched or linear alkyl group of four carbons substituted with a cycloalkyl group of six carbons (*i.e.*, a	not defined (*cf.*. '868 patent, 1:60-5:19, cols. 11-20 (Table 1) and Examples 1-23). Application Ser. No. 06/878,391: Office

U.S. Patent No. 5,147,868 Claim Limitation	Claims at Issue	MERCK		RANBAXY	
		CONSTRUCTION	INTRINSIC EVIDENCE	CONSTRUCTION	INTRINSIC EVIDENCE
		ten carbon atoms wherein a non-terminal methylene can be replaced by oxygen, sulfur or SO2, where said substituents are selected from the group consisting of halogen or cycloalkyl of three to six carbon atoms, with the proviso that, when said alkyl is substituted by said cycloalkyl, X is not more than ten total carbon atoms, with the further proviso that not more than six hydrogens of said alkyl can be substituted by said halogen, and with the further proviso that the carbon adjacent to the carbonyl cannot be tertiary;"		cyclohexyl group), a branched or linear alkyl group of five carbons substituted with a cycloalkyl group of five carbons (*i.e.*, a cyclopentyl group), a branched or linear alkyl group of six carbons substituted with a cycloalkyl group of four carbons (*i.e.*, a cyclobutyl group), and a branched or linear alkyl group of seven carbons substituted with a cycloalkyl group of three carbons (*i.e.*, a cyclopropyl group).	Action dated Nov. 6, 1986; Amendment under 37 C.F.R. §1. 116 received April 6, 1987; Office Action dated July 24, 1987; Amendment under 37 C.F.R. §1.116 dated Oct. 30, 1987; Office Action dated February 7, 1988; Amendment under 37 C.F.R. §1.116 dated May 24, 1988; Application Ser. No. 07/244,527: Preliminary Amendment dated January 23, 1989; Office Action dated March 14, 1990; Amendment dated August 6, 1980; Office Action dated October 12, 1990; Application Ser. No. 07/641,317: Preliminary Amendment dated Jan. 14, 1991; Office Action

U.S. Patent No. 5,147,868 Claim Limitation	Claims at Issue	MERCK		RANBAXY	
		CONSTRUCTION	INTRINSIC EVIDENCE	CONSTRUCTION	INTRINSIC EVIDENCE
					dated March 20, 1991; Amendment and Response dated September 23, 1981; Office Action dated December 9, 1991; Application Ser. No. 07/839,725: Preliminary Amendment and Response dated Feb. 19, 1992; Examiner Interview Summary dated March 30, 1992; Notice of Allowability dated March 30, 1992.
Y	1	"Y" needs no construction. The claim defines "Y" to mean: "cycloalkyl of three to six carbon atoms, unsubstituted or substituted with one or two substituents where said substituents are	'868 patent, col. 1, ln. 45 - col. 5, ln. 10; col. 10, ln. 45 - col. 38, ln. 8; col. 38, lns. 9-66 (Claim 1).	Y includes at least: cyclopropyl, cyclobutyl, cyclopentyl, and cyclohexyl, unsubstituted or substituted with one or two substituents including alkyl of one to four carbon atoms, provided that the total	not defined (*cf.* '868 patent, 1:60-5:19, cols. 11-20 (Table 1) and Examples 1-23). Application Ser. No. 06/878,391: Office Action dated Nov. 6, 1986; Amendment under 37 C.F.R. §1. 116 received April 6, 1987;

U.S. Patent No. 5,147,868 Claim Limitation	Claims at Issue	MERCK		RANBAXY	
		CONSTRUCTION	INTRINSIC EVIDENCE	CONSTRUCTION	INTRINSIC EVIDENCE
		selected from the group consisting of halogen or alkyl of one to four carbon atoms, with the proviso that, when said cycloalkyl is substituted by said alkyl, Y is not more than ten total carbon atoms;"		number of carbon atoms in substituted Y is not more than ten carbon atoms.	Office Action dated July 24, 1987; Amendment under 37 C.F.R. §1.116 dated Oct. 30, 1987; Office Action dated February 7, 1988; Amendment under 37 C.F.R. §1.116 dated May 24, 1988; Application Ser. No. 07/244,527: Preliminary Amendment dated January 23, 1989; Office Action dated March 14, 1990; Amendment dated August 6, 1980; Office Action dated October 12, 1990; Application Ser. No. 07/641,317: Preliminary Amendment dated Jan. 14, 1991; Office Action dated March 20, 1991; Amendment and Response dated September 23, 1981;

U.S. Patent No. 5,147,868 Claim Limitation	Claims at Issue	MERCK		RANBAXY	
		CONSTRUCTION	INTRINSIC EVIDENCE	CONSTRUCTION	INTRINSIC EVIDENCE
					Office Action dated December 9, 1991; Application Ser. No. 07/839,725: Preliminary Amendment and Response dated Feb. 19, 1992; Examiner Interview Summary dated March 30, 1992; Notice of Allowability dated March 30, 1992.
trialkylammonium, quaternary hydroxyalkyl-dialkylammonium, phosphonylalkyl-amino, hydroxyalkylami-no, alkylamidino, N,N-	1	The term "alkyl" means "a paraffinic hydrocarbon group which may be derived from an alkane by dropping one hydrogen from the formula." The term "alkyl" used as part of a larger chemical group or moiety has the meaning understood by persons of ordinary skill in the art in the context	'868 patent, col. 1, ln. 45 - col. 5, ln. 10; col. 21, ln. 44 - col. 23, ln. 23; col. 31, ln. 37 - col. 38, ln. 8; col. 38, lns. 9-66 (Claim 1).	Each alkyl group in each substituent includes a linear, branched, or cyclic alkyl group without limitation as to number of carbon atoms.	not defined (*cf.* '868 patent, 1:60-5:6, cols. 11-20 (Table 1), and Examples 1-23); Claims 1, 9, 22). Application Ser. No. 06/878,391: Office Action dated Nov. 6, 1986; Amendment under 37 C.F.R. §1. 116 received April 6, 1987; Office Action dated July 24, 1987; Amendment under 37 C.F.R. §1.116

U.S. Patent No. 5,147,868 Claim Limitation	Claims at Issue	MERCK		RANBAXY	
		CONSTRUCTION	INTRINSIC EVIDENCE	CONSTRUCTION	INTRINSIC EVIDENCE
dialkyguanidino, alkylcarbonyloxy, alkoxycarbonyl, N,N-dialkylcarbamoyl		of that larger chemical group or moiety.			dated Oct. 30, 1987; Office Action dated February 7, 1988; Amendment under 37 C.F.R. §1.116 dated May 24, 1988; Application Ser. No. 07/244,527: Preliminary Amendment dated January 23, 1989; Office Action dated March 14, 1990; Amendment dated August 6, 1980; Office Action dated October 12, 1990; Application Ser. No. 07/641,317: Preliminary Amendment dated Jan. 14, 1991; Office Action dated March 20, 1991; Amendment and Response dated September 23, 1981; Office Action dated December 9, 1991;

U.S. Patent No. 5,147,868 **Claim Limitation**	**Claims at Issue**	**MERCK**		**RANBAXY**	
		CONSTRUCTION	**INTRINSIC EVIDENCE**	**CONSTRUCTION**	**INTRINSIC EVIDENCE**
					Application Ser. No. 07/839,725: Preliminary Amendment and Response dated Feb. 19, 1992; Examiner Interview Summary dated March 30, 1992; Notice of Allowability dated March 30, 1992.
said one to fifteen carbon alkyl	1	"said two to fifteen carbon alkyl" (typographical error)	'868 Patent, col. 38, lns. 9-66 (Claim 1); U.S. Appl. Ser. No. 07/244,527 (3/14/90 Office Action; 8/8/90 Amendment; 10/12/90 Office Action); U.S. Appl. Ser. No. 07/641,317 (1/14/91 Application; 1/14/91 Preliminary Amendment; 3/20/91 Office Action; 9/23/91 Amendment and Response; 12/9/91 Office Action; 1/28/92 Examiner Interview	said one to fifteen carbon alkyl	'868 patent, 1:55-61; 2: 11-17; 2:47-4:34; Table I, cols 11-20, compounds 2a, 2b, 2c, 3-11, 18-32, 34-38, 40, 42-44; Examples 2, 3, 4, 5, 6, 8, 9, 10, 16; Claim 1. Application Ser. No. 06/878,391: Office Action dated Nov. 6, 1986; Amendment under 37 C.F.R. §1. 116 received April 6, 1987; Office Action dated July 24, 1987; Amendment under 37 C.F.R. §1.116 dated Oct. 30, 1987;

U.S. Patent No. 5,147,868 Claim Limitation	Claims at Issue	MERCK		RANBAXY	
		CONSTRUCTION	INTRINSIC EVIDENCE	CONSTRUCTION	INTRINSIC EVIDENCE
			Summary Record); U.S. Appl. Ser. No. 07/839,725 (2/19/92 Application; 2/19/92 Preliminary Amendment and Response; 3/26/92 Examiner Interview Summary Record; 3/30/92 Notice of Allowability).		Office Action dated February 7, 1988; Amendment under 37 C.F.R. §1.116 dated May 24, 1988; Application Ser. No. 07/244,527: Preliminary Amendment dated January 23, 1989; Office Action dated March 14, 1990; Amendment dated August 6, 1980; Office Action dated October 12, 1990; Application Ser. No. 07/641,317: Preliminary Amendment dated Jan. 14, 1991; Office Action dated March 20, 1991; Amendment and Response dated September 23, 1981; Office Action dated December 9, 1991; Application Ser. No.

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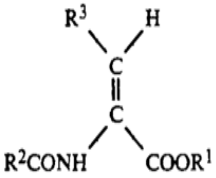
		CONSTRUCTION	INTRINSIC EVIDENCE	CONSTRUCTION	INTRINSIC EVIDENCE
					07/839,725: Preliminary Amendment and Response dated Feb. 19, 1992; Examiner Interview Summary dated March 30, 1992; Notice of Allowability dated March 30, 1992.
2,2-dimethylcyclo-propyl	2, 9	This term needs no construction. The term means "2,2-dimethylcyclopropyl."	'868 patent, col. 38, lns. 67-68 (Claim 2); col. 39, lns. 18-35 (Claim 9); col. 40, lns. 21-23 (Claim 19).	(S)-2,2-dimethylcyclopropyl, (R)-2,2-dimethylcyclopropyl, and mixtures thereof.	'868 patent, 2:18-5:10, Table I, cols. 11-20, Examples 1-23; Application Ser. No. 06/748,300, Office Action of February 24, 1985, Amendment dated May 15, 1986, Communication to the Examiner under 37 C.F.R. §1.56, dated June 5, 1986; Ashton, *et al.* Abstract no. 271 and "poster session, " (ICAAC) Sept. 22-24, 1980; J. E. Blackwood et al., *J. Am. Chem. Soc.*, 90, p. 509 (1968);

U.S. Patent No. 5,147,868 Claim Limitation	Claims at Issue	MERCK		RANBAXY	
		CONSTRUCTION	INTRINSIC EVIDENCE	CONSTRUCTION	INTRINSIC EVIDENCE
					A. Srinavasan et al. *Tetrahedron Lett.*, 891 (1976).
	9	This formula needs no construction. The formula defines the structure illustrated, which shows the Z-stereoconfiguration.	'868 Patent, col. 1, ln. 45 - col. 5, ln. 11; col. 38, lns. 10-66 (Claim 1); col. 39, lns. 18-36 (Claim 9); A. Srinavasan et al. *Tetrahedron Lett.*, 891 (1976).	The formula includes racemates, mixtures, isomers, and enantiomers of the free acid form, salt forms, and ester forms of the compound, with the exception of the E-stereoisomer form.	'868 patent, 2:18-5:10, Table I, cols. 11-20 and Examples 1-23, Claims 1, 9, 19 and 20; Application Ser. No. 06/465,577: Office Action dated February 24, 1984; Response under 37 C.F.R. §1.111 dated July 7, 1984; Office Action dated December 4, 1984; Application Ser. No. 06/748,300, Office Action of February 24, 1985, Amendment dated May 15, 1986, Communication to the Examiner under 37 C.F.R. §1.56, dated June 5, 1986; Ashton, *et al.* Abstract no. 271 and "poster session,"

U.S. Patent No. 5,147,868 Claim Limitation	Claims at Issue	MERCK		RANBAXY	
		CONSTRUCTION	INTRINSIC EVIDENCE	CONSTRUCTION	INTRINSIC EVIDENCE
					(ICAAC) Sept. 22-24, 1980; Application Ser. No. 06/878,391: Office Action dated Nov. 6, 1986; Amendment under 37 C.F.R. §1. 116 received April 6, 1987; J. E. Blackwood et al., *J. Am. Chem. Soc.*, 90, p. 509 (1968); A. Srinavasan et al. *Tetrahedron Lett.*, 891 (1976).
R^1 is hydrogen, loweralkyl of 1-6 carbon atoms, dialkylaminoalkyl, or a pharmaceutically acceptable cation	9	This phrase as a whole needs no construction. The phrase "R1 is hydrogen" needs no claim construction. The term "loweralkyl of 1-6 carbon atoms" needs no construction. The term	'868 patent, col. 1, ln. 45 - col. 2, ln. 45; col. 5, lns. 12-18; col. 39, lns. 18-36 (Claim 9).	R^1 defines three mutually exclusive subgenera: (1) a free acid form in which R^1 is hydrogen, (2) ester forms in which R^1 is loweralkyl of 1-6 carbon atoms, or dialkylaminoalkyl, and (3) salt forms in which R^1 is a pharmaceutically	'868 patent 1:60-5:6, 5:11-19; 2:18-5:10, Table I, cols. 11-20 and Examples 1-23, Claims 1, 19 and 20. Application Ser. No. 06/878,391: Office Action dated Nov. 6, 1986; Amendment under 37 C.F.R. §1. 116 received April 6, 1987; Office Action dated July

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		CONSTRUCTION	INTRINSIC EVIDENCE	CONSTRUCTION	INTRINSIC EVIDENCE
		"dialkylaminoalkyl" needs no construction. The term "pharmaceutically acceptable cation" is defined by the parties above.		acceptable cation.	24, 1987; Amendment under 37 C.F.R. §1.116 dated Oct. 30, 1987; Office Action dated February 7, 1988; Amendment under 37 C.F.R. §1.116 dated May 24, 1988; Application Ser. No. 07/244,527: Preliminary Amendment dated January 23, 1989; Office Action dated March 14, 1990; Amendment dated August 6, 1980; Office Action dated October 12, 1990; Application Ser. No. 07/641,317: Preliminary Amendment dated Jan. 14, 1991; Office Action dated March 20, 1991; Amendment and Response dated September 23, 1981; Office Action dated

U.S. Patent No. 5,147,868 Claim Limitation	Claims at Issue	MERCK		RANBAXY	
		CONSTRUCTION	INTRINSIC EVIDENCE	CONSTRUCTION	INTRINSIC EVIDENCE
					December 9, 1991; Application Ser. No. 07/839,725: Preliminary Amendment and Response dated Feb. 19, 1992; Examiner Interview Summary dated March 30, 1992; Notice of Allowability dated March 30, 1992.
7-(L-2-amino-2-carboxyethylthio)-2-(2,2-dimethylcyclo-propanecarbox-amido)-2-heptenoic acid	19	This term means "the free acid, ester and salt forms of 7-(L-2-amino-2-carboxyethylthio)-2-(2,2-dimethylcyclo-propanecarboxamido)-2-heptenoic acid."	'868 Patent, col. 5, lns. 11-19; col. 8, ln. 42-col. 9, ln. 45; col. 10, lns. 25-44; col. 19, lns. 35-67; col. 20, ln. 35-col. 23 ln. 23; col. 34, lns. 9-68; col. 38, lns. 9-66 (Claim 1); col. 39, lns. 19-35 (Claim 9); col. 40, lns. 21-25 (Claims 19-20).	the free acid form of 7-(L-2-amino-2-carboxyethylthio)-2-(2,2-dimethylcyclo-propanecarboxamido)-2-heptenoic acid, excluding a pharmaceutically acceptable cation, the free acid form including the (S)-(2,2-dimethylcyclo-propanecarboxamido) form, the (R)-(2,2-	'868 patent 1:60-5:6, 5:11-19; 2:18-5:10, Table I, cols. 11-20 , Claims 1, 9, 19 and 20. '868 patent, 2:18-5:10; Table I, cols. 11-20; Claims 1, 9, 19 and 20; Application Ser. No.

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		CONSTRUCTION	INTRINSIC EVIDENCE	CONSTRUCTION	INTRINSIC EVIDENCE
				dimethylcyclo-propanecarboxamido) form, and mixtures thereof.	06/465,577: Office Action dated February 24, 1984; Response under 37 C.F.R. §1.111 dated July 7, 1984; Office Action dated December 4, 1984; Application Ser. No. 06/748,300, Office Action of February 24, 1985, Amendment dated May 15, 1986, Communication to the Examiner under 37 C.F.R. §1.56, dated June 5, 1986; Ashton, *et al.* Abstract no. 271 and "poster session," (ICAAC) Sept. 22-24, 1980; Application Ser. No. 06/878,391: Office Action dated Nov. 6, 1986; Amendment under 37 C.F.R. §1. 116 received April 6, 1987; J. E. Blackwood et al., *J. Am. Chem. Soc.*, 90, p.

U.S. Patent No. 5,147,868 Claim Limitation	Claims at Issue	MERCK		RANBAXY	
		CONSTRUCTION	INTRINSIC EVIDENCE	CONSTRUCTION	INTRINSIC EVIDENCE
					509 (1968); A. Srinavasan et al. *Tetrahedron Lett.*, 891 (1976).
the sodium, potassium calcium or magnesium salt form	20	This term needs no construction. This term means "the sodium, potassium, calcium, or magnesium salt form."	'868 Patent, col. 5, lns. 11-19; col. 8, ln. 42-col. 9, ln. 45; col. 10, lns. 25-44; col. 19, lns. 35-67; col. 20, ln. 35-col. 23 ln. 23; col. 34, lns. 9-68; col. 38, lns. 9-66 (Claim 1); col. 39, lns. 19-35 (Claim 9); col. 40, lns. 3-8 (Claims 13-14); col. 40, lns. 21-25 (Claims 19-20).	the sodium, potassium calcium or magnesium salt form, excluding the free acid form.	'868 patent 1:60-5:6, 5:11-19; 2:18-5:10, Table I, cols. 11-20, Claims 1, 9, 19 and 20.
R^2	22	"R^2" needs no construction. The claim defines "R^2" to mean: "cycloalkyl of three to six carbon atoms substituted by two alkyl substituents of one to three carbon atoms each, with the proviso that R^2 cannot contain more	'868 patent, col. 40, lns. 28-33 (Claim 22).	R^2 includes at least: cyclopropyl substituted by two substituents of one, two, or three carbon atoms each; cyclobutyl substituted by two substituents of one, two, or three carbon atoms each;	not defined (*cf.* '868 patent, 1:60-5:6, cols. 11-20 (Table I), Examples 1-23; Claims 1-22). Application Ser. No. 06/878,391: Office Action dated Nov. 6, 1986; Amendment under 37 C.F.R. §1. 116 received April 6, 1987;

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		CONSTRUCTION	INTRINSIC EVIDENCE	CONSTRUCTION	INTRINSIC EVIDENCE
		than ten carbon atoms."		cyclopentyl substituted by one substituent of one, two, or three carbon atoms and by one substituent of one or two carbon atoms; and cyclohexyl substituted by one substituent of one, two, or three carbon atoms and by one substituent of one carbon atom, or cyclohexyl substituted by one substituent of one or two carbon atoms and by one substituent of one or two carbon atoms.	Office Action dated July 24, 1987; Amendment under 37 C.F.R. §1.116 dated Oct. 30, 1987; Office Action dated February 7, 1988; Amendment under 37 C.F.R. §1.116 dated May 24, 1988; Application Ser. No. 07/244,527: Preliminary Amendment dated January 23, 1989; Office Action dated March 14, 1990; Amendment dated August 6, 1980; Office Action dated October 12, 1990; Application Ser. No. 07/641,317: Preliminary Amendment dated Jan. 14, 1991; Office Action dated March 20, 1991; Amendment and Response dated September 23, 1981;

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		CONSTRUCTION	INTRINSIC EVIDENCE	CONSTRUCTION	INTRINSIC EVIDENCE
					Office Action dated December 9, 1991; Application Ser. No. 07/839,725: Preliminary Amendment and Response dated Feb. 19, 1992; Examiner Interview Summary dated March 30, 1992; Notice of Allowability dated March 30, 1992.

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